PP# F 7300

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

SEP 2 1988

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUJECT: PP#8F3592/FAP#8H5550 - Abamectin (Avermectin B_1) on Citrus - Evaluation of Method of Evaluation Report of June 14, 1988 on the Meat and Milk Method - MRID Nos. 406368-01 and -02 - DEB Nos. 3929 and 3920

FROM: V. Frank Boyd, Ph.D., Chemist
Tolerance Petition Section 2
Dietary Exposure Branch
Health Effects Division (TS-769C)

TO: George T. LaRocca; PM 15
Insecticide-Rodenticide Branch
Registration Division (TS-767C)

and

Toxicology Branch
Health Effects Division (TS-769C)

THRU: Charles L. Trichilo, Ph.D., Chief
Dietary Exposure Branch
Health Effects Division (TS-769C)

OPP's Analytical Chemistry Laboratory (ASC/COB/BUD) has completed a method evaluation on Abamectin (Avermectin B_1) and its delta-8,9-isomer in milk, beef liver, and beef muscle. The method tested was the Merck, Sharp and Dohme Method No. 32A, June 10, 1987.

Milk was fortified at 1 and 5 ppb levels for both the parent and its isomer. Beef liver was fortified at 10 and 30 ppb for each chemical, and beef muscle was fortified at 10 and 30 ppb for the parent and 5 and 10 ppb for the metabolite. The recoveries are tabulated as follows:

Recovery of Avermectin B_1 and its Delta 8,9-Isomer from Meat and Milk

Commodity	Chemical Added	ppb Added	Percent Recovery
Beef Liver	Avermectin B_1a	10	75.2, 75.6
		30	93.1, 92.8
	Delta-8,9-Isomer	10	82.1, 91.1
		30	83.2, 103.9
Beef Muscle	Avermectin B_1a	10	72.0, 79.3
		30	63.8, 74.3
	Delta-8,9-Isomer	5	118.4, 117.6
		10	79.1, 71.4
Milk	Avermectin B_1a	1	133.6, 122.1
		5	108.5, 102.5
	Delta-8,9-Isomer	1	124.3, 119.8
		5	109.2, 99.8

All controls were N.D. (none detected) at a sensitivity of 5 ppb in muscle, 10 ppb in liver, and 1 ppb in milk.

In using the method for enforcement the Analytical Chemist mentions the extent of time required for analysis--2 days and overnight HPLC for milk and 3 days and overnight HPLC for meat. Also, the derivatizing agent, trifluoroacetic anhydride, was found to be unstable, unless freshly prepared, and must be used within a half-hour of its preparation.

DEB Conclusions

The Method No. 32A, June 10, 1987, for the analysis of Avermectin B_1a and its delta-8,9-isomer is adequate as a monitoring method for meat and milk. Since completion of the EPA method validation, a revised method, Method No. 32A - Revision (MRID No. 406368-01, DEB Nos. 3929 and 3930), April 21, 1988, has been submitted by the petitioner, but only adds recovery data for Avermectin B_1b and its delta-8,9-isomer. Since Avermectin B_1b has not been of concern in the quantitation of Abamectin residues, this revised method will become a part of the PP#8F3592 file at this time.

Recommendations

Method No. 32A, June 10, 1987, should be made available to interested parties. DEB is therefore sending copies of this method to FDA and USDA so that these enforcement agencies may use the method for monitoring, when appropriate, and so that they may have an opportunity to comment on the monitoring method prior to the establishment of a permanent tolerance. This method should not be included in PAM II until the permanent tolerances have been established. A copy of the method is also being sent to PMSD so that it will be readily available under FOI.

DEB continues to recommend against the establishment of tolerances for Avermectin B_1 in or on cotton (PP#7F3500), citrus (PP#8F3592/FAP#8H5550), and meat and milk, until the deficiencies enumerated in the evaluation of these petitions have been satisfied.

Attachments:
1. PAM II Cover Sheet
2. Method No. 32A, June 10, 1987
3. Method Evaluation Report from ACS/COB/BUD
4. Method Trial Request

cc (With Attachment 1, Only): PM 15, PP#7F300, PP#8F3592, D. Marlow, R.F., Circu., Reviewer - F. Boyd, TOX, Robert E. Thompson (RTP), FDA - P. Corneliussen, USDA - R. Ellis

cc (With Attachments 1-4): PMSD/ISB - Eldredge, M. Bradley,

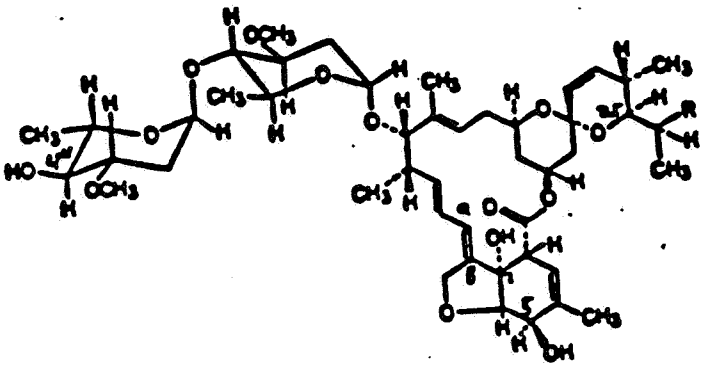
RDI:J.H. Onley; 8/19/88:R.D. Schmitt 8/22/88,
TS-69:DEB:F.Boyd:CM#2:RM 810:557-7484:Typist Kenco, 8/25/88
Edited by, MT, 8/30/88.

ATTACHMENT 1

Acceptable Name: Avermectin B_1 = Avermectin B_1a (80%) and Avermectin B_1b (20%)
[Avermectin B_1a is Avermectin A_1a,5-0-demethyl;
Avermectin B_1b is Avermectin A_1a,5-0-demethyl-25-de(1-methylpropyl-25(1-methylethyl)]

Pesticide Registration Section 180

Structure:



Avermectin B_1
R = C_2H_5 for B_1a
R = CH_3 for B_1b

Other Names: Abamectin
MK-936
Agrimec
Affirm

Petitioner: Merck, Sharp and Dohme Research Laboratories
Division of Merck and Company, Inc.
Hillsborough Road
Three Bridges, NJ 08887

Method No.: 32A, HPLC-Fluorescence Assay for Avermectin B_1a, B_1b, and the Avermectin B_1a Delta-8,9-Isomer in Bovine Tissues and Milk.

Pesticide Petition: PP#8F3592

Product Application: Meat (beef liver and beef muscle) and milk

Detection Limit:

	Percent	Isomer
Beef Liver	10 ppb	10 ppb
Beef Muscle	10 ppb	5 ppb
Milk	1 ppb	1 ppb

Method Trial Report: PP8F3592 - Avermectin on Citrus: Method Evaluation for Meat and Milk Report 8/29/88.

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		5	109.2, 99.8

Notes:

1. The derivatizing agent, trifluoroacetic anhydride, was found to be stable for 30 minutes after preparation.

2. One chemist can run a set of six samples in 2 1/2 days for milk and 3 1/2 days for meat.